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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/322,875	05/28/1999	ANAN CHUNTHARAPAI	I1669.19US03	8566

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/14/2001

09

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/322,875

Applicant(s)

Chuntharapai et al.

Examiner

DeCloux, Amy

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Oct 3, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-18, 20, 21, 23, 24, and 33-55 is/are pending in the applica

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from considera

5) ☒ Claim(s) 13-18 is/are allowed.

6) ☒ Claim(s) 1-10, 12, 20, 21, 23, 24, and 33-55 is/are rejected.

7) ☒ Claim(s) 11 is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirem

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

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### DETAILED ACTION

Note: The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.

1. Applicant's amendment, mailed 9-28-01 (Paper No. 18), is acknowledged.
2. The rejections of record can be found in the previous Office Action, mailed 3-28-01 (Paper No. 16).

In view of applicant's amendment and remarks, mailed 9-28-01, the 112 first deposit rejection, the 112 first written description rejection as applied to now canceled claim 19, has been withdrawn, as have the 112 second paragraph rejections and the 103(a) rejections. However, the 103 art rejections have been maintained, essentially for the reasons of record.

3. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of *section 102* of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. MAINTAINED Claims 1-5, 9-10, 21, 23-24, 33-34, 38-40, 42-43, 47-48 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al. (56 on form 1449 filed 2/10/00) in view of Campbell (U on form PTO-892 filed with the previous

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office action).

MAINTAINED Claims 1-10, 20-21, 23-24, 36-43, 45-48 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al. (56 on form 1449 filed 2/10/00) in view of Campbell (U on form PTO-892 filed with the previous office action) and Gussow et al (V on form PTO-892 filed with the previous office action).

Applicants traverse the rejections on the grounds that the Pan reference does not teach or suggest that the referenced anti-DR4 antibodies specifically bind to the recited DR4 sequence. However the examiner notes that specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY ); and In re Burckel 201 USPQ 67 (CCPA) . Since the recited sequence is disclosed by the instant specification on page 9 as the extracellular domain of DR4, it would be obvious to one of ordinary skill in view of the teachings of Campbell and Gussow to have made said antibodies to the extracellular portion of DR-4.

Therefore, although applicant's arguments have been carefully considered, they are not deemed persuasive, and the rejection is maintained, essentially for the reasons of record.

#### NEW GROUNDS OF REJECTION

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

7. Claim 12 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in part (3) of said claim because no verb is recited. Inserting the word "binds" after the term "PTA-99" is one way to overcome this rejection.

8. Claims 35, 44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al. (56 on form 1449 filed 2/10/00) in view of Campbell (U on form PTO-892 filed with the previous office action) as applied to Claims 1-5, 9-10, 21, 23-24, 33-34, 38-40, 42-43, 47-48 and 52-54 above, and further in view of Janeway et al (Immunobiology 4th Edition (1997)).

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Campbell and Pan teach as described in Section 6 of the previous office action. However, neither teaches human anti-DR4 antibodies.

Janeway et al teaches that the problem of rapidly developing antibodies directed to antibodies from non human species used in therapy of humans can be circumvented by making immunoglobulin receptors that are encoded by human genes in rag knockout mice transgenic for human immunoglobulin receptors encoded on YACs(see especially page 544, first paragraph).

Therefore, it would have been *prima facie* obvious to a person of obvious skill in the art at the time the invention was made to have applied the teachings of Janeway et al regarding human monoclonal antibodies to the teachings of Pan et al and Cambell et al to obtain human antibodies directed against the DR4 macromolecule taught by Pan for use in therapy since Cambell et al. teaches that it is customary for any group working on a macromolecule to make monoclonal antibodies to it, and since Janeway et al teaches that the problem of rapidly developing antibodies directed to antibodies from non human species used in therapy of humans can be circumvented by making immunoglobulin receptors that are encoded by human genes in rag knockout mice transgenic for human immunoglobulin receptors encoded on YACs.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

9. It is noted that in the description of Figures on page 8 of the instant specification "1H5" is used to refer to antibody 1H5.25.9 in the description of Figure 8A, while the designation "1H5" is also used to refer to the antibody 1H5.24.9 in the description of Figure 9. The examiner is trying to determine if there are two different antibodies (1H5.25.9 and 1H5.24.9) or if there is only one antibody and one label is a typo. The description of the Table in Figure 17, refers to the antibody 1H5.24.9 which is denoted as antibody 1H5.24.9 in said Table and in Example 8 of the instant specification. However the Table disclosed on page 35 of the instant specification denotes 1H5.25.9 as being the deposited antibody.

10. Claims 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 12-18 appear to contain allowable subject matter.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-

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5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Group 1640, Technology Center 1600  
December 12, 2001

*David A. Saunders*

DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT ~~182~~ 1644